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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,269

02/17/2004

Keith M. Grispo

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

06/19/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/780,269	<b>Applicant(s)</b> GRISPO, KEITH M.	
	<b>Examiner</b> ANDREW M. GILBERT	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 57-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/21/2008 has been entered.

### ***Acknowledgments***

2. This office action is in response to the reply filed on 4/21/2008.
3. In the reply, the Applicant cancelled claims 1-17, 40-56 and added new claims 57-61.
4. Thus, claims 57-61 are pending for examination.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 57-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Medrad, Inc., "Stellant CT Injection System", Operation Manual Catalog #SOM 700 EN, 2003, 88 pages - hereafter, "Stellant". Stellant discloses a method of using a dual head injector (pg 11, 16), the method comprising: mounting a first syringe that is prefilled (pg 32-56; wherein the Examiner notes that the syringe is explicitly disclosed as being capable of being prefilled - see 3-31, parts 2-3 "if the syringe was previously filled with contrast...", also see 3-37, part "to re-install the syringe" in that case the syringe is also considered prefilled) with contrast media to the injector; mounting a second syringe to the injector (pg 32-56); coupling a first section of Y-tubing to the first syringe and coupling a second section of the Y-tubing to the second syringe (3-30); initiating a programmed purge protocol of the injector while the first and second syringes are mounted to the injector and while the first and second sections of the Y- tubing are coupled to the first and second syringes (3-30, parts 3-7; where it is explicit that after the syringes are connected to the y-connector that the device is primes and the purge routine is performed to ensure that all air is purged; it is explicit that the syringes are not connected to the patient prior to purging and priming), respectively, wherein the programmed purge protocol comprises: advancing a first plunger drive ram of the injector to move a plunger of the first syringe a first predetermined distance (pg 34-36), wherein the advancing of the first plunger drive ram is sufficient to purge all air from the first syringe and the first section of Y-tubing and fill the first section of the Y-tubing with contrast media (pg 34-36); and advancing a second plunger drive ram of the injector to move a plunger of the second syringe a second predetermined distance (pg 30, 34-36;

especially pg 36), wherein the advancing of the second plunger drive ram is sufficient to purge all air from the second section of the Y- tubing (pg 30, 34-36; the Examiner further notes that unless specifically detailed otherwise the steps of method claims can be preformed in any order. As claims, either the contrast or saline syringe (ie 1<sup>st</sup> or 2<sup>nd</sup> syringe) may be purged first); and initiating a programmed injection procedure that includes injecting contrast media into the patient (pg 34-52), wherein the programmed injection procedure occurs: after the programmed purge protocol is completed; while the first and second syringes are mounted to the injector; and while the first and second sections of the Y-tubing are coupled to the first and second syringes, respectively (pg 34-52); wherein a combination of the advancing of the first plunger drive ram and the advancing of the second plunger drive ram results in a purge of substantially all air from the first and second syringes and the Y-tubing (pg 30, 34-52; and discussions above); wherein the advancing of the first plunger drive ram occurs before the advancing of the second plunger drive ram (pg 30, 34-52; and discussions above); wherein the advancing of the second plunger drive ram comprises filling the second section of the Y-tubing with saline; wherein the advancing of the second plunger drive ram comprises filling the second section and a third section of the Y-tubing with saline (pg 30, 34-52; and discussions above).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emig et al (6471674) in view of Stellant. Emig et al discloses a method of using a dual head injector (Fig 1), the method comprising: mounting a first syringe that is prefilled (300, col 2, lns 19-20; col 5, lns 38) with contrast media to the injector; mounting a second syringe to the injector (500); coupling a first section of T-tubing (450) to the first syringe and coupling a second section of the Y-tubing to the second syringe (Fig 1); initiating a programmed purge protocol of the injector while the first and second syringes are mounted to the injector and while the first and second sections of the Y- tubing are coupled to the first and second syringes (col 6, lns 9-19); and initiating a programmed injection procedure that includes injecting contrast media into the patient (Summary; col 6), wherein the programmed injection procedure occurs: after the programmed purge protocol is completed; while the first and second syringes are mounted to the injector; and while the first and second sections of the Y-tubing are coupled to the first and second syringes, respectively (col 6); wherein a combination of the advancing of the first plunger drive ram and the advancing of the second plunger drive ram results in a purge of substantially all air from the first and second syringes and the Y-tubing (col 6); wherein the advancing of the second plunger drive ram comprises filling the second section of the Y-tubing with saline; wherein the advancing of the second plunger drive ram comprises filling the second section and a third section of the Y-tubing with saline (col 6).

9. However, Emig et al does not disclose a Y-connector and respectively, wherein the programmed purge protocol comprises: advancing a first plunger drive ram of the injector to move a plunger of the first syringe a first predetermined distance, wherein the advancing of the first plunger drive ram is sufficient to purge all air from the first syringe and the first section of Y-tubing and fill the first section of the Y-tubing with contrast media; and advancing a second plunger drive ram of the injector to move a plunger of the second syringe a second predetermined distance, wherein the advancing of the second plunger drive ram is sufficient to purge all air from the second section of the Y-tubing and wherein the advancing of the first plunger drive ram occurs before the advancing of the second plunger drive ram.

10. Stellant teaches that it is known to have a y-connector and wherein the programmed purge protocol comprises: advancing a first plunger drive ram of the injector to move a plunger of the first syringe a first predetermined distance (pg 34-36), wherein the advancing of the first plunger drive ram is sufficient to purge all air from the first syringe and the first section of Y-tubing and fill the first section of the Y-tubing with contrast media (pg 34-36); and advancing a second plunger drive ram of the injector to move a plunger of the second syringe a second predetermined distance (pg 30, 34-36; especially pg 36), wherein the advancing of the second plunger drive ram is sufficient to purge all air from the second section of the Y- tubing (pg 30, 34-36; the Examiner further notes that unless specifically detailed otherwise the steps of method claims can be preformed in any order. As claims, either the contrast or saline syringe (ie 1<sup>st</sup> or 2<sup>nd</sup> syringe) may be purged first) and wherein the advancing of the first plunger drive ram

occurs before the advancing of the second plunger drive ram (pg 30, 34-52; and discussions above) for the purpose of expelling all trapped air from the syringes, connectors, and tubing to minimize air embolization risks. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the purge programming as taught by Emig et al with the purge routine as taught by Stellant for the purpose of expelling all trapped air from the syringes, connectors, and tubing to minimize air embolization risks.

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 57-61 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/  
Examiner, Art Unit 3767  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767